

REMARKS/ARGUMENTS

Claims 1-17, 22-24 and 27-30 remain in this application, and new claims 31 through 55 have been added by amendment. Claims 18-21 and 25-27 have been withdrawn from consideration pursuant to the restriction/election requirement previously imposed. Claims 1, 4, 7, 12, 15, 22, and 28 remain in independent form, and new independent claims 31, 42, 47, 48, 49, 50, 52, 53, 54 and 55 have been added by this amendment.

The Office Action noted that the oath or declaration was defective. A new oath and declaration is enclosed herein and applicant respectfully requests that this new oath and declaration be entered for the present application.

Claim 12 was objected to for having a misspelling of the word "hemorrhage." This misspelling has been corrected and applicant respectfully asserts that this objection has been overcome.

Claims 1-14 were rejected under 35 U.S.C. 112, first paragraph for being non-enabling for the prevention of thrombosis, thrombo-embolic troubles, blood coagulation disorders, and thrombosis in a patient with hemorrhage risk. The term "preventing" has been removed from all of the claims and applicant asserts that this rejection has been overcome.

Claims 4-6 were rejected under 35 U.S.C. 112, second paragraph for indefiniteness of the phrase "thrombo-embolic trouble." This phrase has been replaced in the subject claims by the phrase "thrombo-embolic diseases" which is a technical term familiar to those of skill in the art. Support for this amendment can be found at lines 19-20 on page 2 of the present application which note "Thrombo-embolic disease of arterial or venous origin remains one of the main reasons of death in developed countries." Accordingly, applicant asserts that this rejection has been overcome.

Claims 1-2, 4-5, 7-8, 10-13, 15-16, 22-23, and 28-29 were rejected under 35 U.S.C. 102(a) as anticipated by Mar et al., *Betaine in Wine: Answer to the French Paradox*, Med Hypothesis, 1999 Nov; 53(5):383-5 (Mar). This application claims priority to Belgian Patent Application Serial No. 9900144 filed on March 2, 1999 and its corresponding PCT application. This Belgian patent application disclosed the same invention now claimed in the rejected claims and is identical to the PCT application. Accordingly, Mar is not prior art to the present application and applicant respectfully requests that this rejection be withdrawn.

Claims 7-9 were rejected under 35 U.S.C. 102(b) as anticipated by Salamone et al., *Changes in blood Coagulation in Experimental Subacute Poisoning With P-Chlorobenzene. The Influence of Some Lipotropic Factors*, Folia Meidca (Naples), 1960, 43, 259-66 (Salamone). These claims have been amended to recite that the glycine betaine is administered on a daily basis to humans. Salamone fails to teach or suggest such limitations. Furthermore, Salamone merely determines the appearance of the disturbance of blood coagulation in the diagnosis of p-dichlorobenzene intoxication which is very different from the invention covered by the present claims. In the specification, thrombosis was defined according to Virchow's Triad and betaine antithrombotic activity as reducing blood coagulation activation resulting in thrombin formation. In contrast, Salamone does not teach or suggest that betaine reduces one of the parameters of Virchow's Triad but instead indicates that betaine in combination with choline and vitamin B12 provides a protective effect against prolongation of blood coagulation (i.e. hypocoagulation) induced by subacute poisoning by p-dichlorobenzene and olive oils. Accordingly, applicants assert that this rejection has been overcome.

Claims 1-15, 16-17, 22-24, and 28-30 were rejected under 35 U.S.C. 103(a) as obvious over U.S. Patent No. 5,880,098 to Haussinger (Haussinger) and further in view of WO 97/06795 to Kalvinish et al.

(Kalvinish). Haussinger discloses a method of treating complications resulting from ischemia, hypoxia, or oxidative stress with a composition comprising therapeutically effective amounts of an osmolyte and a thrombolytic agent. This essentially teaches away from the present claims which treat patients at risk of thrombosis and thrombo-embolic diseases in order to avoid the occurrence of pathological events that could lead to ischemia and the like. In short, Haussinger discloses treating the symptom or consequence of a disorder, the present application treats patients to avoid the cause or the underlying disorder. Kalvinish discloses a pharmaceutical composition containing Gamma-Butyrobetaine which is not equivalent to glycine betaine. In support of this argument, applicant has attached an Declaration attesting to the differences and the significance of these differences between glycine betaine and gamma-butyrobetaine. Accordingly, applicant respectfully asserts that this rejection has been overcome.

Additionally, applicant has attached a second Declaration in support of the patentability of the presently-pending claims. Accordingly, entry of this Declaration under 37 CFR§ 1.132 is respectfully requested. It is noted that numbered paragraph 8G references a digest of tests. This digest is provided as Exhibit 2 although it is not noted in the Declaration that this Exhibit is provided as an exhibit.

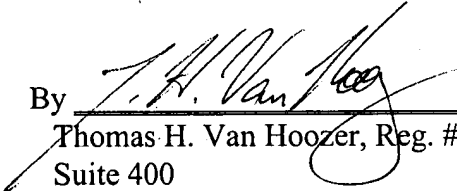
For all of the foregoing reasons, applicant submits that the specification and the claims are now in proper form, and that all of the claims define patentability over the prior art. Accordingly, early issuance of the Notice of Allowance is courteously requested. Should any additional fees be due in connection with

this submission, they may be charged to deposit account 19-0522. Any issues which remain and may be resolved by a telephone conference may directed to the undersigned at 1-800-445-3460.

Respectfully submitted,

HOVEY WILLIAMS LLP

By


Thomas H. Van Hoozer, Reg. #32761
Suite 400
2405 Grand Boulevard
Kansas City, Missouri 64108
(816) 474-9050

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